

PATENT COOPERATION TREATY

PCT

REC'D 03 JUL 2001

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

Applicant's or agent's file reference 53 124 V	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP00/05631	International filing date (day/month/year) 19/06/2000	Priority date (day/month/year) 18/06/1999	
International Patent Classification (IPC) or national classification and IPC A61N5/10			
Applicant AEA TECHNOLOGY QSA GMBH et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

Date of submission of the demand 06/12/2000	Date of completion of this report 29.06.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Schießl, W Telephone No. +49 89 2399 7436



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EXAMINATION REPORT**

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I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
Description, pages:

1-17 as originally filed

Claims, No.:

1-30 as originally filed

Drawings, sheets:

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:

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the drawings, sheets:

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):
(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- the entire international application.
- claims Nos. 24-30.

because:

- the said international application, or the said claims Nos. 24-30 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet
- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- no international search report has been established for the said claims Nos. 24-30.
2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:
- the written form has not been furnished or does not comply with the standard.
- the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 8, 9, 12, 16, 17, 23

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No: Claims 1-7, 10, 11, 13-15, 18-22

Inventive step (IS) Yes: Claims
No: Claims 1-23

Industrial applicability (IA) Yes: Claims 1-23
No: Claims

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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Section III

Claims 24-30 relate to subject-matter mentioned in Rule 67.1(iv) PCT, in particular to a method of therapeutical and surgical treatment of the human or animal body ('method for vascular radiation treatment ..'). Under terms of Article 34(4)(a)(i) PCT an International Preliminary Examining Authority is not required to carry out an examination of such claims.

Section V

1 Reference is made to the following documents (D) cited in the International Search Report:

- D1: US-A-5 683 345 (HILLSTEAD RICHARD A ET AL) 4 November 1997 (1997-11-04) cited in the application
- D2: WO 98 36790 A (CONDADO MED DEVICES CORP ;CONDADO JOSE ANTONIO R (VE)) 27 August 1998 (1998-08-27)
- D3: WO 97 18012 A (LOCALMED INC) 22 May 1997 (1997-05-22)
- D4: WO 97 19724 A (IBT TECHNOLOGY PARTNERS ;CONIGLIONE ROY (US)) 5 June 1997 (1997-06-05)
- D5: US-A-4 940 452 (LINK RAINER ET AL) 10 July 1990 (1990-07-10)
- D6: EP-A-0 993 843 (TERUMO CORP) 19 April 2000 (2000-04-19)

2 Novelty (Article 33(2) PCT)

2.1 The present International Application does not meet the requirements of Article 33(2) PCT because the subject-matter of claims 1 and 19 is not new:

Document D1 discloses an apparatus for endovascular radiation treatment (col. 9, l. 65 to col. 12, l. 23, figs. 3, 4), said apparatus comprising an elongated catheter (142) having a proximal end portion, a distal end portion and a lumen (144) extending therebetween for receiving a radiation source, and a radiation source (22) which comprises treating elements (128) comprising a radiation emitting element (138) and means for containment (128, 132, 134) of said emitting element, wherein said treating elements are sequentially, directly and movably

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attached to each other (col. 10, l. 32 et seq., fig. 3, and hence all features of claims 1 and 19. It should be noted that even a single seed 22 anticipates the subject-matter of claim 1 (cf. VIII, 1 below).

- 2.2 D2-D4 also make known a radiation source according to claims 1 and 19 (D2: p. 62, ll. 7-26, p. 75, l. 25 et seq., figs. 44A, F; D3: p. 36, l. 32 et seq., figs. 36-38; D4: p. 9, ll. 33, 34, p. 6, ll. 4-7, p. 18, ll. 21-26, figs. 4, 5).
- 2.3 Various dependent claims do not meet the requirements of the PCT in respect of novelty, since
D1 further discloses
- the features of a radiation source as recited in claims 2-7, 10 and 11 (col. 10, ll. 1, 2, 35-40, 46-49, fig. 3),
 - an apparatus comprising a containment vessel and an x-ray fluoroscopy device as defined in claims 20-22 (col. 6, ll. 56-61; col. 12, ll. 22, fig. 2A), and D2 anticipates
 - mechanically linked treating elements in the sense of claims 11, 13- 15 (figs. 44A, F), whereas D3 and D4 show
 - a flexible single joining member according to claim 18 (D3: figs. 36, 37, flexible housing 198; D4: fig. 4, part 403).

3 Inventive step (Article 33(3) PCT)

- 3.1 The remaining dependent claims do not meet the requirements of the PCT in respect of inventive step, as
- D5 discloses a magnetic coupling / a magnetic means of a single source (as covered by claim 1) to a flexible transfer wire within a catheter for conventional interstitial brachytherapy (col. 3, ll. 20-53, figs. 1-4) and hence all structural features of claims 1, 8, 9, 12, 19 and 23, so that in view of the existing sources / catheters for use in endovascular radiation treatment (cf. D1-D4) the skilled person would consider a size reduction of the apparatus described in D5 to enable an endovascular use, and
 - the alternative mechanical links defined in claims 16 and 17 are straightforward design options the skilled person would select without the

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exercise of inventive skill.

- 3.2 It is annotated, that two or more treating elements linked by magnetic forces to each other as claimed as one alternative in claim 8 are neither known from, nor rendered obvious by, the available prior art, since in particular D5 gives no indication of a magnetic link between two or more seeds. Accordingly, the subject-matter of an amended independent claim based in accordance with Article 34(2)(b) PCT on claims 1 and 8 as mentioned above would have appeared to meet the requirements of Article 33 PCT (cf. also VIII, below).

Section VI

Certain published documents (Rule 70.10):

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (<i>valid claim</i>) (day/month/year)
D6	19/04/00	13/10/99	14/10/98 27/10/98

D6 describes a source and an apparatus according to claims 1 and 19 of the present application (col. 11, ll. 29-46, col. 14, ll. 36-56, figs. 5, 11) and thus anticipates the subject-matter of these claims. The validity of the claimed priorities could not be checked.

Section VII

- 1 Independent apparatus claims should be in the two-part form in accordance with Rule 6.3(b) PCT.
- 2 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 3 The units of measure 'rad' and 'mCi' employed on page 10 are not additionally expressed in terms of the units stipulated by Rule 10.1(a) PCT that is in 'Gy' and 'Bq'.

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Section VIII

The present international application does not meet the requirements of Article 6 PCT:

- 1 In claim 1, it is said that 'one or more treating elements .. are .. linked to each other and/or to a transfer wire'. In case of an 'or'-excluded transfer wire and only one treating element being present, no link is provided at all and accordingly a conventional single seed is claimed.
- 2 Further in claim 1, the term 'seeds' defined in parenthesis as a reference sign does not limit the scope of the claim. Hence, said term should have been replaced by 'treating elements' throughout the claims.
- 3 Claim 17 refers to 'the receiving section' and should therefore only have been combined with claim 15.
- 4 Independent claim 19 comprises a radiation source according to claim 1, which is separately included in claim 20 thereby rendering claim 20 unclear. Claims 19 and 20 should have been combined that is claim 19 should have recited an apparatus comprising a radiation source according to claims 1-18.
- 5 The technical features / function of the 'magnetic means' as defined in claim 23 are unclear (apart from being magnetic).
- 6 The description on page 14, paragraph 3, mentioning a guidewire (15) in a separate lumen appears to be in contradiction to fig. 4, wherein part (15) indicates a transfer wire.